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EXAMINER	
HELM, CARALYNNE E	
ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,590	SATO ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The amended claim now recites that the "nonionic osmotic pressure regulating agent is present in an amount up to 4% by weight"; however, there is not written bases for the upper limit being 4% by weight. Paragraph 53 of the specification does discuss a contemplated range for this component, but is expressed on a mmol/kg basis.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 recites the limitation "the amount of the cationic

monomer is in the range…" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim since there is no reference to a cationic monomer in any of its parent claims.

Since claim 18 depends from 17, the limitations drawn to the cationic monomer are not considered in the application of prior art to claim 18.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 8-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Dobrozsi et al. (U.S. Patent No. 6,503,955 – previously cited).

Dobrozsi et al. teach a solution with a polyoxyalkylene copolymer of ethylene oxide with propylene oxide (poloxamer/pluronic) and propylene glycol, in the absence of an ionic compound (see column 5 lines 37-63 and example XIII vehicle formulation; instant claims 8-10). Therefore claims 8-9 are unpatentable over Dobrozsi et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquires of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uno et al. (JP 10-197831 – see IDS) in view of Wichterle et al. (US patent No. 3,220,960- see IDS).

Uno et al. teach a contact lens with a polymer consisting of a 2-hydroxyethyl methacrylate (HEMA - hydrophilic monomer having a hydroxyl group in its molecule), 2-hydroxy-3-methacryloyloxypropyl triammonium chloride (MAPTAC - monomers having a nitrogen atom in its side chain), mono-(2-acryloyloxyethyl) acid phosphate (MOAP), triethylene glycol dimethacrylate (monomer copolymerizable with the other monomers) (see paragraph 19 and table 1 example 6). The MAPTAC is taught present at 5% (see table 1 example 6; instant claim 3). In addition, Uno et al. teach that mono-(2-acryloyloxyethyl) acid phosphate and 2-methacryloyloxyethyl acid phosphate (MOEP - Formula I/II) are functional equivalents (see paragraph 12; instant claim 1). Uno et al. do not teach that the resulting lens also contains a cationic group containing drug.

Wichterle et al. teach a molded gel (ophthalmic lens) made of a copolymer of acrylamide (monomers having a nitrogen atom in its side chain) at 15%, ethylene glycol monomethacrylate (hydrophilic monomer having a hydroxyl group in its molecule) and ethylene glycol dimethacrylate (monomer copolymerizable with the other monomers) (see column 4 lines 7 and column 5 lines 61-70; instant claim). These materials are quite similar in nature to those used by Uno et al. Further, Wichterle et al. teach that the resulting gel is loaded with penicillin (cationic group containing drug with tertiary amine) (see column 5 lines 760-73; instant claim 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use MOEP instead of MOAP at 10 wt% in the lens preparation of Uno et al. Since it was known to include penicillin in a contact lens for its subsequent delivery, it would have been obvious to one of ordinary

skill in the art at the time of the invention to include it in the lens of Uno et al. Therefore claims 1, 3, and 5 are unpatentable over Uno et al. in view of Wichterle et al.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uno et al. in view of Wichterle et al. as applied to claims 1, 3, and 5 above, and further in view of Ohmura et al. (US Patent No. 4,604,425)

Uno et al. in view of Wichterle et al. make obvious a contact lens with penicillin, and a copolymer made of HEMA, MAPTAC, MOEP, and triethylene glycol dimethacrylate. Uno et al. teach the presence of a quaternary ammonium salt that is radically polymerizable in the polymer (see paragraph 12). In the example discussed, MAPTAC serves this function in the polymer. Uno et al. in view of Wichterle et al. do not teach that (meth)acrylamide is capable of performing the same function in the polymer.

Ohmura et al. teach a hydrophilic copolymer preparation where a set of vinyl monomers that are radically polymerizable is one of its monomers (see column 11 lines 51-54). In this set, MAPTAC, meth(acrylamide) and quaternary ammonium salts of methacrylic acid are taught to be functionally equivalent (see column 11 lines 63-64 and column 11 lines 67-column 12 line 37). Since (meth)acrylamide can be used in the same role as the general class (quaternary ammonium salt that is radically polymerizable) and specific monomers taught by Uno et al., it would have been obvious to one of ordinary skill in the art to employ (meth)acrylamide instead of MAPTAC in the contact lens preparation of Uno et al. in view of Wichterle et al. Thus claims 1 and 4 are obvious over Uno et al. in view of Wichterle et al. and Ohmura et al.

Claims 1-2, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uno et al. in view of Wichterle et al. as applied to claims 1, 3, and 5 above, and further in view of Janda et al. (U.S. Patent No. 4,640,936 – previously cited) and Andersson et al. (Contact Dermatitis 1999 41:254-259).

Uno et al. in view of Wichterle et al. make obvious a contact lens with penicillin and a copolymer made of HEMA, MAPTAC, MOEP, and triethylene glycol dimethacrylate (see instant claim 1, 13 and 16). The MOEP would be employed at the same proportion taught for MOAP, namely 10 wt% (see table 1 and example 6; instant claim 16). This modified reference does not teach the presence of a monomer of formula III along with the MOEP.

Andersson et al. discusses components used in the most commonly used dental adhesives (see abstract). Interestingly, these hydrogel based compositions often use the same monomer constituents as contact lenses such as HEMA, triethylene dimethacrylate and ethylene methacrylate (see abstract and page 256 column 1 paragraph 1).

Janda et al. teach the use of both 2-methacryloyloxyethyl dihydrogen phosphate (MOEP - formula II) and bis-(methacryloyloxyethyl) hydrogen phosphate (formula III) in a polymeric preparation for biological use (dental adhesive) (see example and claim 1; instant claim 2). Since it was known to use both a monomer of formula II and formula III for applications where either is also suitable by itself, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ them both in the lens

preparation of Uno et al. in view of Wichterle et al. Although the ratio of the formula II to formula III compound taught by Janda et al. is 100% by weight, the claimed ratio is quite close to this value and would have been achieved by the routine experimentation of one of ordinary skill in the art (see instant claim 16). Therefore claims 1-2, 13, and 16 are obvious over Uno et al. in view of Wichterle et al., Andersson et al. and Janda et al.

Claims 1-2, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uno et al. in view of Wichterle et al., Andersson et al. and Janda et al. as applied to claims 1-2, 13, and 16 above, and further in view of Ohmura et al.

Uno et al. in view of Wichterle et al., Andersson et al. and Janda et al. make obvious a contact lens with penicillin, and a copolymer made of HEMA, MAPTAC, MOEP, formula III, and triethylene glycol dimethacrylate. Uno et al. teach the presence of a quaternary ammonium salt that is radically polymerizable in the polymer (see paragraph 12). In the example discussed, MAPTAC serves this function in the polymer. Uno et al. in view of Wichterle et al., Andersson et al. and Janda et al. do not teach that (meth)acrylamide is capable of performing the same function in the polymer.

Ohmura et al. teach a hydrophilic copolymer preparation where a set of vinyl monomers that are radically polymerizable is one of its monomers (see column 11 lines 51-54). In this set, MAPTAC, meth(acrylamide) and quaternary ammonium salts of methacrylic acid are taught to be functionally equivalent (see column 11 lines 63-64 and column 11 lines 67-column 12 line 37). Since (meth)acrylamide can be used in the same role as the general class (quaternary ammonium salt that is radically

polymerizable) and specific monomers taught by Uno et al., it would have been obvious to one of ordinary skill in the art to employ (meth)acrylamide instead of MAPTAC in the contact lens preparation of Uno et al. in view of Wichterle et al., Andersson et al. and Janda et al. Thus claims 1-2, and 13-15 are obvious over Uno et al. in view of Wichterle et al., Andersson et al., Janda et al. and Ohmura et al.

Claims 1-2, 13, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uno et al. in view of Wichterle et al., Andersson et al. and Janda et al. as applied to claims 1-2, 13, and 16 above, and further in view of Kamishita et al. (US Patent No. 4,983,386).

Uno et al. in view of Wichterle et al., Andersson et al. and Janda et al. make obvious a contact lens with a drug, and a copolymer made of HEMA, MAPTAC, MOEP, formula III, and triethylene glycol dimethacrylate with the claimed proportions and ratios of monomers. The modified reference does not teach naphazoline nitrate specifically as the drug.

Kamishita et al. teach that naphazoline nitrate is a know drug that is used to treat ailments of the eye, (see column 3 lines 10-13; instant claim 18). Although Kamishita et al. teach this compound being delivered via gel ointment, it would have been obvious to one of ordinary skill in the art at the time of the invention to use another known means of delivery, such as in a contact lens as taught by Uno et al. in view of Wichterle et al., Andersson et al. and Janda et al. Thus it would have been obvious to use naphazoline

nitrate instead of penicillin the contact lens of Uno et al. in view of Wichterle et al., Andersson et al. and Janda et al.

Claims 6, 7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sulc et al. (U.S. Patent No. 5,270,415) in view of Aiache et al. (U.S. Patent No. 6,713,080).

Sulc et al. teach a contact lens as a drug delivery system where a cationic and anionic monomer pair is used (see column 5 lines 3-6; instant claim 6). Specifically Sulc et al. teach the lens made from a copolymer of N,N-dimethylaminoethyl methacrylate (anionic monomer) methacrylic acid (cationic monomer), 2-hydroxyethyl methacrylate (hydrophilic monomer) and ethylene glycol dimethacrylate (monomer copolymerizable with the other monomers) (see column 2 lines 66-67, column 3 lines 3-6 and 58-61, column 4 lines 22-25, and example 1; instant claim 6). Sulc et al. teach the anionic to cationic polymer ratio in one embodiment to be approximately 90 mol% (92 mol% as calculated by examiner from example 17). It would therefore have been obvious to one of ordinary skill in the art at the time of the invention to use the contact lens formulation of Sulc et al. with an anion-cationic monomer ratio of 90mol%. In addition, since Sulc et al. teach compositions with a molar ratio of anionic to cationic monomers that spans 20 mol%, it would have been obvious to one of ordinary skill in the art at the time of the invention to adjust this ratio, depending on the particular anion-cation pair such that the desired lack of debris retention is achieved on the lens surface (see examples 1 and

17). Sulc et al. do not teach particular drugs to use in the embodiment where the lens is also a drug delivery device.

Aiache et al. teach the inclusion of a sodium diclofenac, an anionic and carbonyl group containing drug, in a poly(2-hydroxyethyl methacrylate) hydrogel contact lens (see example 7; instant claims 6 and 7). Thus in view of the teachings of Aiache et al. it would have been obvious to one of ordinary skill in the art at the time of the invention to employ sodium diclofenac in the invention of Sulc et al. Thus claims 6, 7, and 11 are obvious over Sulc et al. in view of Aiache et al.

Claims 6, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sulc et al. in view of Aiache et al. as applied to claims 6,7, and 11 above and in further view of Kato et al. (US Patent No. 5,945,121).

Sulc et al. in view of Aiache et al. make obvious an anionic drug containing contact lens with a copolymer consisting of a hydrophilic monomer, cationic monomers, anionic monomers and a monomer copolymerizable with these components such that the molar ratio of anionic monomer to cationic monomer is 40 to 80 mol%. Sulc et al. in view of Aiache et al. do not teach a water soluble azulene as one such anionic drug delivered from their device.

Kato et al. teach that sodium azulene sulfonate (water soluble azulene) is a know drug that is used to treat ailments of the eye, such as inflammation (see column 2 lines 7-14; instant claim 12). Although Kato et al. teach this compound being delivered via eye drops, it would have been obvious to one of ordinary skill in the art at the time of the

invention to use another known means of delivery, such as in a contact lens as taught by Aiache et al. and Sulc et al. Therefore it would have been obvious to use sodium azulene sulfonate instead of the particular drug taught by Aiache et al. in the device of Sulc et al. in view of Aiache et al. Thus claims 6, 11, and 12 are obvious over Sulc et al. in view of Aiache et al. and Kato et al.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dow et al. (US Patent No. 6,589,922 in view of Schultz et al. (US Patent No. 6,534,687).

Dow et al. teach a composition that is free of ionic compounds and made from the combination of purified water, poloxamer 123, glycerin, sorbitol, as well as a set of nonionic organic alcohols and esters (see example 1; instant claim 8). The poloxamer is taught to be present at 0.4wt%, while the glycerin is present at 2 wt% (see example 1; instant claim 10). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The intended use of the composition as recited by claim 8 is as a storing solution for the claimed ophthalmic lens. The composition of Dow et al. is capable of performing this function. Dow et al. teach their composition to be intended as a mild topical cleanser for sensitive skin, but do not teach a particular pH that would be suitable for such an application (see lines 30-31).

Schultz et al. teach that the typical pH of skin is 5-6 and that this acidic mantle is usually removed by soap upon washing (see column 2 lines 61-65). Normal skin quickly regenerates this acidic environment, but sensitive skin does not which leads to skin irritation (see column 2 lines 61-65). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the formulation of Dow et al. with the slightly acidic pH of skin so that it would not alter the pH of sensitive skin upon use and greatly reduce the likelihood of skin irritation. Therefore claims 8 and 10 are obvious over Dow et al. in view of Schultz et al.

Response to Arguments

Applicants' arguments, filed September 17, 2008, have been fully considered but they are not deemed to be persuasive.

Regarding rejections under 35 USC 102(a):

Applicant argues that because several formulations taught by Dobrozsi et al. do not meet their envisioned or claimed limitations, that the reference does not teach the claimed composition. Nothing of record precludes the vehicle composition of Dobrozsi et al. in example XIII, as cited, from serving as a storage solution for the lens of claim 6. In addition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Although applicant

cites several formulations that fall outside the boundary of their claimed composition, the vehicle in example XIII does meet their claim limitations. Furthermore, applicant does not dispute that the vehicle in this example teaches their ionic compound free composition.

Regarding rejections under 35 USC 103(a):

Applicants argue that it would not have been obvious to one of ordinary skill to gather from the teachings of Sulc et al. that their polymer composition could be formed as a contact lens and used as a drug delivery system. Sulc et al. do teach that their composition is suitable for applications as a contact lens and as a drug delivery system (see column 5 lines 3-6). It was well known at the time of the invention that contact lenses could be used as drug delivery systems. At least ten years before the filing of applicant's priority document, contact lenses were contemplated and utilized as drug delivery devices (see Chiou - US Patent No. 5,182,258 - column 3 lines 5-10). In references published the same year as applicant's priority document, contact lenses with different properties (ionic or nonionic) were still being utilized for drug delivery (see Schultz et al. B- US Patent No. 6,410,045 - column 2 line 66-column 3 line 10, column 3 line 67-column 4 line 4, and column 5 lines 44-52). Even if the recitation of Sulc et al. is not interpreted as direct guidance to utilize a contact a lens as a drug delivery system, it certainly would have been obvious to one of ordinary skill in the art at the time of the invention given their knowledge and the teachings of Sulc et al.

Applicant argues that the there would be no reason for one of ordinary skill in the art to alter the composition proportions explicitly taught by Sulc et al. and that the upper boundary for the molar ratio of anionic to cationic monomer of 90mol% was critical to the invention. As discussed in the rejections above, Sulc et al. teach a molar ratio of anionic to cationic monomers that spans 20 mol% when different sets of anion-cation pairs are used. Thus depending on the pair of monomers selected, it would have been obvious to modify their proportions to achieve the contact lens that attracts little debris, as intended by Sulc et al. The particular reasoning for the alteration may be different than that of applicant, but the same end of routine optimization would be occur such that the claimed proportion of anion to cation would be achieved. Applicant currently only asserts the criticality of the 90 mol% ratio of anion to cation. They also teach that when this molar ratio is exceeded that drug is not retained in the lens. Based upon the teachings of Schultz et al. B it is not necessary that a lens have a charge opposite that of the drug to be held. This fact is demonstrated in their teaching of a polymacon (nonionic) lens carrying and delivering timolol maleate, a cationic drug (see column 5 lines 29-35). Thus applicant's assertions are unsubstantiated by data that corroborates them and conflict with information in the prior art.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615